

1 ADAM A. REEVES (NYBN 2363877)
2 Attorney for the United States,
2 Acting Under Authority Conferred By 28 U.S.C. § 515

3 HALLIE HOFFMAN (CABN 210020)
Chief, Criminal Division

5 JEFF SCHENK (CABN 234355)
JOHN C. BOSTIC (CABN 264367)
ROBERT S. LEACH (CABN 196191)
6 Assistant United States Attorneys

150 Almaden Boulevard, Suite 900
San Jose, California 95113
Telephone: (408) 535-5589
FAX: (408) 535-5066
john.bostic@usdoj.gov

10 | Attorneys for United States of America

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,) CASE NO. 18-CR-00258 EJD
Plaintiff,)
v.) **UNITED STATES' OPPOSITION TO**
ELIZABETH HOLMES and RAMESH) **DEFENDANTS' MOTION TO COMPEL**
“SUNNY” BALWANI,) Date: June 28, 2019
Defendants.) Time: 10:00 a.m.
) Court: Hon Edward J. Davila

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	FACTUAL & PROCEDURAL BACKGROUND	2
	A. Defendants' Fraud and the Pending Criminal Charges.....	2
	B. The Prosecution's Document Production to Date.....	2
	C. Defendant Balwani's Previous Attempts to Obtain Additional Agency Documents	3
	D. The Prosecution's Good-Faith Efforts to Obtain the Requested Materials	3
	E. The Agencies' Agreements to Produce Further Documents.....	5
III.	ARGUMENT	8
	A. Defendants' motion seeks documents not in the prosecution's possession, custody, or control.	8
	B. The defense's arguments regarding the content and materiality of the requested documents are speculative.	10
	C. The government has no obligation to obtain and produce documents held by state agencies not involved in the criminal investigation.	11
	D. The government has already produced discoverable materials received from SEC	12
	E. An order requiring the government to comply with its discovery obligations is unnecessary and impracticable.	13
IV.	CONCLUSION	15

TABLE OF AUTHORITIES

	Page(s)
1 Cases	
4 <i>SEC v. Reyes</i> , 5 No. C, 06-04435 CRB, 2007 WL 528718 (N.D. Cal. Feb. 13, 2007)	13
5 <i>United States v. Armstrong</i> , 6 517 U.S. 456 (1996).....	10, 11
6 <i>United States v. Bryan</i> , 7 868 F.2d 1032 (9th Cir. 1989)	9
7 <i>United States v. Cadet</i> , 8 727 F.2d 1453 (9th Cir.1984)	10, 11
8 <i>United States v. Chavez-Vernaza</i> , 9 844 F.2d 1368 (9th Cir.1988)	11
9 <i>United States v. Dominguez-Villa</i> , 10 954 F.2d 562 (9th Cir.1992)	12
10 <i>United States v. Flores</i> , 11 No. 08-0730-WHA, 2011 WL 1100137 (N.D.Cal. Mar. 24, 2011)	14
11 <i>United States v. Fort</i> , 12 478 F.3d 1099 (9th Cir.2007)	11
12 <i>United States v. Gatto</i> , 13 763 F.2d 1040 (9th Cir. 1985)	11
13 <i>United States v. Jennings</i> , 14 960 F.2d 1488 (9th Cir.1992)	14
14 <i>United States v. Little</i> , 15 753 F.2d 1420 (9th Cir.1984)	10
15 <i>United States v. Lucas</i> , 16 841 F.3d 796 (9th Cir. 2016)	14
16 <i>United States v. Mandel</i> , 17 914 F.2d 1215 (9th Cir.1990)	10, 11
17 <i>United States v. Muniz-Jaquez</i> , 18 718 F.3d 1180 (9th Cir.2013)	10
18 <i>United States v. Salyer</i> , 19 271 F.R.D. 148 (E.D. Cal. 2010)	9
19 <i>United States v. Santiago</i> , 20 46 F.3d 885 (9th Cir. 1995)	9
20 <i>United States v. Stever</i> , 21 603 F.3d 747 (9th Cir. 2010)	9
21 <i>United States v. W.R. Grace</i> , 22 401 F. Supp. 2d 1069 (D. Mont. 2005).....	9
22 <i>United States v. Zone</i> , 23 403 F.3d 1101 (9th Cir.2005)	10
23 <i>United States v. Zuno-Arce</i> , 24 44 F.3d 1420 (9th Cir. 1995)	9
25 Statutes	
26 15 U.S.C. § 78x(f)(1)(A).....	13
27 18 U.S.C. 1905	6
27 18 U.S.C. § 6	13
27 18 U.S.C. § 3500.....	13
28 21 U.S.C. 331(j).....	6
28 21 U.S.C. 360j(c)	6

1	28 U.S.C. § 515.....	1, 15
2	Rules	
3	Fed. R. Crim. P. 16(a)(2)	13, 14
	Federal Rule of Criminal Procedure 17	1, 10
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		
26		
27		
28		

1 **I. INTRODUCTION**

2 The Court should deny Defendant's motion to compel because none of the materials covered by
 3 the motion are in the possession of the prosecution. Instead, the materials are held by other government
 4 agencies, such that any production or disclosure is at those agencies' discretion. Rather than avail
 5 themselves of Federal Rule of Criminal Procedure 17 to request these documents directly from the
 6 custodian agencies, Defendants seek the Court's assistance in forcing the prosecution to go beyond its
 7 discovery obligations and do Defendants' investigatory work for them. Defendants' arguments suffer
 8 from serious flaws.

9 For example, Defendants ask the Court to treat the federal government as a monolith and assume
 10 that every government agency has automatic access to the documents of every other. In reality, the
 11 federal government is comprised of numerous agencies and components, each of which has its own
 12 independent mission and a significant degree of autonomy over its records and resources. Defendants
 13 claim that the prosecution somehow hand-picked documents from agencies like FDA and CMS during
 14 earlier stages of its investigation, selecting materials favorable to its case and leaving behind exculpatory
 15 evidence. In fact, the prosecution merely tailored its requests to these agencies to capture the documents
 16 most relevant to this case without imposing undue burden on those agencies. Defendants demand that
 17 the government produce documents on the grounds that those documents are favorable and material to
 18 the defense, but their arguments on these points are speculative. Ignoring the work product doctrine,
 19 Defendants' requested documents also encompass internal communications and notes constituting the
 20 work product of an agency engaged in ongoing litigation against Balwani. If granted, Defendants'
 21 motion threatens to impermissibly expand the government's discovery obligations and make the
 22 prosecution responsible for the document productions of third parties over which it has no control. The
 23 Court should avoid this unfair result.

24 The simplest reason to deny Defendants' motion, however, is that it largely seeks relief that the
 25 prosecution has already provided. Before Defendants filed their motion to compel, the government
 26 offered to use its best efforts to obtain and produce the documents covered by the motion. Although
 27 Defendants rejected that offer, the government nonetheless submitted written requests to the custodian
 28 agencies and has recently learned that, subject to reasonable conditions, the agencies are willing to

1 produce the majority of the requested documents. The government has also offered to make case agent
 2 interview notes available for Defendants' inspection, and to seek to review SEC's interview notes for
 3 *Brady* material—accommodations that will sufficiently protect Defendants' rights. A court order is not
 4 necessary where it would do nothing more than restate the government's discovery obligations or
 5 compel action the government has already taken.

6 II. FACTUAL & PROCEDURAL BACKGROUND

7 A. Defendants' Fraud and the Pending Criminal Charges

8 In this case, Defendants' fraudulent conduct took place over several years and resulted in
 9 hundreds of millions of dollars lost by investor victims as well as the defrauding of doctors and patients
 10 who believed Defendants' representations that Theranos's tests were accurate and reliable. The
 11 Superseding Indictment (Dkt. No. 39) alleges schemes to defraud the above groups of victims, and
 12 specifies misrepresentations Defendants made in furtherance of those schemes. For example, the
 13 Indictment alleges that Defendants claimed Theranos's proprietary analyzer was capable of performing
 14 the full range of clinical tests using small blood samples drawn from a finger stick and producing results
 15 more accurate and reliable than those yielded by conventional methods, when Defendants knew the
 16 company's proprietary analyzer had far more limited abilities. The Indictment similarly alleges that
 17 Defendants made false or misleading statements on subjects like Theranos's financial health, Theranos's
 18 partnership with Walgreens, Theranos's business with the United States Department of Defense, the
 19 purported validation of Theranos devices by pharmaceutical companies and research institutions, and the
 20 FDA approval status of Theranos's analyzer and tests. Contrary to Defendants' claims, the
 21 government's case does not rest solely on evidence from FDA and CMS. Indeed, Defendants' repeated
 22 misrepresentation concerning FDA was just one of many underlying their scheme to defraud.

23 B. The Prosecution's Document Production to Date

24 Over the course of its investigation in this matter, the government has collected millions of pages
 25 of evidence from numerous sources, including: (1) investor victims who parted with substantial sums of
 26 money based on false information from Defendants; (2) doctor and patient victims who purchased and
 27 relied on Theranos's tests based on false information about the accuracy of those tests; (3) Theranos
 28 itself and former employees of the company; (4) other corporate and academic entities that explored

1 partnerships with Theranos; and (5) components of the federal government that interacted with Theranos
 2 as part of their regulatory responsibilities or other missions.

3 The government has already produced the vast majority of all of the materials that it has obtained
 4 from the sources above, and is preparing to produce the rest. As part of its production, the government
 5 provided to the defense approximately 300,000 pages of documents collected from FDA and Centers for
 6 Medicare and Medicaid Services (CMS). The government obtained those documents pursuant to
 7 requests targeting materials relevant to Theranos whether the evidence was inculpatory or exculpatory.
 8 (See, e.g., Wade Decl. Exhs. 6 & 8). In total, the government's production to date includes more than
 9 twenty million pages of documents. As the government collects additional materials in connection with
 10 its ongoing investigation, it will continue to provide those documents to the defense in a timely manner.

11 **C. Defendant Balwani's Previous Attempts to Obtain Additional Agency Documents**

12 The pending motion does not represent Defendants' first attempt to obtain the requested
 13 documents from the agencies. Months before joining the instant motion, Balwani served civil subpoenas
 14 on FDA and CMS, seeking documents in numerous broad categories encompassing internal agency
 15 materials and correspondence with other agencies, legislators, journalists, entities in the healthcare
 16 industry, and other laboratories. The government understands that counsel for Balwani subsequently
 17 engaged in a lengthy meet and confer process with counsel for FDA and CMS. Although that process
 18 revealed significant disagreements over the proper scope of the subpoenas, Balwani has not moved to
 19 compel production under those subpoenas. As an alternative means to obtaining these documents,
 20 Defendants have now demanded that the prosecution retrieve them from the custodian agencies and
 21 produce them.

22 Despite their ability to issue subpoenas under Rule 17 of the Federal Rules of Criminal
 23 Procedure compelling third parties to disclose relevant evidence, neither Defendant has issued a
 24 subpoena in the criminal case to any of the federal agencies addressed in their motion.

25 **D. The Prosecution's Good-Faith Efforts to Obtain the Requested Materials**

26 In late March 2019, defense counsel sent a letter asking the government to obtain and produce
 27 additional materials from several government agencies, including FDA, CMS, SEC, Department of
 28 Health and Human Services (DHHS), and Department of Defense (DOD). (Wade Decl. Exh. 5, pp. 8-
 GOVT. OPPOSITION TO MOTION TO COMPEL

1 10).

2 In early April 2019, the government met and conferred with defense counsel regarding the
3 defense's requests for additional documents from FDA, CMS, and DOD. Following the initial
4 discussion with the defense, the prosecution contacted counsel for FDA, CMS, and DOD in order to
5 inquire about the agencies' ability and willingness to produce additional documents in this case. During
6 those conversations, government counsel confirmed its understanding that the prosecution did not have
7 access to the requested documents held by these agencies.

8 For example, more than one agency raised concerns regarding the large volume of documents
9 previously provided to the prosecution earlier in its investigation of this case, with agency
10 representatives understandably wary of expending agency resources on additional broad document
11 requests that overlapped with those earlier productions. That drain on resources was compounded by
12 technical limitations facing the agencies. CMS, for instance, noted that it did not have access to
13 document database software, and was relying on DOJ's Litigation Technology Service Center to host
14 documents being collected in response to Balwani's civil subpoena. At least one agency also informed
15 government counsel that applicable law might limit its discretion to disclose additional documents post-
16 Indictment, since the case did not involve charges under certain statutes relevant to the agency's
17 purview. The agencies also explained their obligations to protect confidential documents held in
18 connection with their sensitive missions as regulatory and defense organizations. In some cases, those
19 responsibilities would require the agencies to make the sharing of documents conditional on the
20 prosecution's promise not to disclose that sensitive information further absent agency permission. The
21 agencies recognized that such a condition would be problematic given the government's discovery
22 obligations and general practice of producing such evidence directly to the defense. In that same vein,
23 agency representatives discussed the need for a waiver from the entity controlling Theranos's legal
24 rights before they would be permitted to disclose sensitive information received from the company
25 during its operation. Government counsel was informed that Balwani's counsel had agreed to obtain
26 such a waiver at the beginning of 2019 but had not yet succeeded.

27 Shortly after receiving this information from the agencies, government counsel had another
28 discussion with the defense. During that conversation, counsel for the government explained that it had

1 already produced the documents it received from FDA, CMS, and DOD and did not have access to
 2 materials still in the agencies' possession. Although not obligated to do so, the government offered to
 3 make good-faith efforts to obtain the documents requested by the defense. In connection with that offer,
 4 the government cautioned defense counsel that, because any additional production by FDA, CMS, or
 5 DOD would be at the agencies' discretion, the prosecution could not guarantee that it would be able to
 6 obtain and produce all agency documents responsive to Defendants' requests.¹ Despite the lack of such
 7 a guarantee, government counsel believed that it was worthwhile to seek the requested documents from
 8 the agencies, and asked the defense to hold off on filing a motion to compel so that process could play
 9 out. Defense counsel rejected this offer immediately and indicated that they planned to proceed with the
 10 instant motion.

11 After Defendants filed their motion, government counsel continued to confer with
 12 representatives for FDA and CMS. The government's discussions with the two agencies yielded
 13 information regarding the appropriate format of any additional document requests and the contact
 14 information of the individuals best situated to respond to such requests.

15 On May 9, 2019, the government sent letters to FDA and CMS formally requesting additional
 16 documents in connection with this case. (Bostic Decl. Exhs. A & B). In making those requests, the
 17 government adopted verbatim Defendants' descriptions of the requested documents. The government
 18 subsequently held follow-up discussions with FDA and CMS representatives to provide contextual
 19 information for the requests and to encourage a timely response.

20 **E. The Agencies' Agreements to Produce Further Documents**

21 On June 7, 2019, FDA responded to the prosecution's request for additional documents, agreeing
 22 to produce responsive materials. (Bostic Decl. Exh. C). In its letter, FDA addresses its earlier
 23 production of approximately 40,000 pages, and lays out its expectations regarding the categories of
 24 responsive documents likely remaining in its possession. The letter also reports that, in response to the
 25 subpoena it received from Balwani in the SEC action, it has already used relevant keywords to search
 26

27

¹ Defendants' characterizations of information relayed by the government during this
 28 conversation are incomplete and misleading. The government contests these descriptions and has
 provided a more complete account of the agencies' concerns above.

1 the records of at least 45 custodians—including current and former FDA employees—and has collected
 2 more than 62,000 documents. FDA states that it is now in the process of reviewing those documents for
 3 responsiveness as well as for privileged or otherwise protected information. FDA agrees that, in
 4 connection with that ongoing review, it will produce to the government documents responsive to the six
 5 categories comprising the pending requests. Because the pending document requests did not include any
 6 time limitation, FDA intends to take the reasonable step of limiting its production to the eight-year time
 7 period covered by Balwani’s broader subpoena in the SEC civil case.

8 Completing this production will require FDA to address and overcome several challenges. As
 9 noted in the letter, the agency does not have the ability to de-duplicate its newly collected documents
 10 against its previous productions or against the rest of the newly collected set, requiring manual
 11 comparison so as to avoid duplication of review effort. This process will presumably slow FDA’s
 12 production somewhat and increase the already significant burden on the agency. Because the
 13 government’s requests call for internal agency correspondence, FDA will need to locate and redact
 14 privileged information from its documents before production. FDA also is prohibited by statute from
 15 releasing trade secrets and confidential commercial information obtained through its regulatory
 16 authority. (*Id.* [citing 21 U.S.C. 331(j), 21 U.S.C. 360j(c), and 18 U.S.C. 1905]). Accordingly, the
 17 agency will review its production to remove or redact such information as necessary.² Despite these
 18 obstacles and the amount of resources it will take to address them, FDA estimates that it will be in a
 19 position to begin a rolling production of responsive documents within one month.

20 On June 10, 2019, CMS responded to the prosecution’s document requests. (Bostic Decl.
 21 Exh. D). In its letter, CMS notes that it has already expended significant resources to collect and

23 ² Although Defendants were formerly affiliated with Theranos, they both left the company
 24 before it ceased operations, and no longer have the authority to authorize FDA to release Theranos’s
 25 trade secrets and confidential commercial information. Theranos itself previously provided a waiver
 26 that authorized FDA’s previous productions. Upon its dissolution, Theranos entered into an assignment
 27 for the benefit of creditors, with the assignee now holding Theranos’s rights and assets. The Theranos
 28 assignee has not given a waiver allowing FDA to produce confidential information in the recently
 requested documents. The government understands that Balwani’s counsel was recently able to
 negotiate such a waiver from the assignee permitting FDA and CMS to release confidential Theranos
 information in response to the subpoena in the SEC case. (Bostic Decl. Exh. F). If defense counsel is
 able to secure a similar waiver for the criminal case, the FDA may be able to produce additional
 documents and at a faster pace, thought it will still need to capture and redact third-party confidential
 information from its production.

1 produce more than 260,000 pages of documents to DOJ in this case, and correctly points out that the
 2 government's latest document requests overlap with that earlier production. Like FDA, CMS reports
 3 that it has already begun preparing a production of documents in response to Balwani's subpoena in the
 4 SEC action, and will produce those materials—including documents responsive to the six categories in
 5 the government's request—in the criminal case as well. Based on CMS's knowledge of its files, its
 6 letter summarizes what it has already produced and previews what it is likely to have remaining with
 7 respect to responsive documents. Except for one category for which CMS has no responsive documents,
 8 CMS agrees to retrieve and produce external and/or internal documents pursuant to the government's
 9 request to the extent such documents have not already been produced.

10 CMS's production will require the agency to devote substantial resources to the collection and
 11 review of potentially responsive documents. Additionally, because some of the documents responsive to
 12 the government's requests are internal agency communications and other sensitive items, they implicate
 13 CMS's interest in protecting the confidentiality of those materials. Accordingly, CMS asks that the
 14 Court enter a protective order that will shield these documents from misuse and unnecessary public
 15 disclosure. The government supports CMS's request for a protective order and, to facilitate production,
 16 will work with the defense to prepare an appropriate proposed order for the Court's consideration.

17 Along with CMS's response letter, the government received a declaration from a representative
 18 of the California Department of Public Health's (CDPH) Laboratory Field Services. (Bostic Decl. Exh.
 19 E). On behalf of CDPH, that declaration affirms that CDPH had only a small number of CMS
 20 documents relevant to the 2013 CLIA survey of Theranos, which CMS will produce. CDPH is currently
 21 not aware of any communications, either internally or with CMS, regarding the 2013 survey, but has
 22 begun an email search to verify that no such communications exist.

23 Although the prosecution is unable to control the collection and production efforts of the above
 24 agencies, it will continue to work toward obtaining the requested documents from the agencies in order
 25 to produce those materials to the defense.

26 //

27

1 **III. ARGUMENT**

2 **A. Defendants' motion seeks documents not in the prosecution's possession, custody, or**
 3 **control.**

4 The discovery record shows that the government has taken a broad view to discovery, exceeding
 5 its discovery obligations in producing documents in its possession. As described above, the government
 6 has collected tens of millions of pages of evidence in this case. Its treatment of those documents shows
 7 that the government is not motivated by a desire to deprive the defense of information or provide the
 8 bare minimum. On the contrary, the government has produced the vast majority of the collected
 9 materials to both Defendants without engaging in the lengthy review that would be necessary to
 10 determine that each of those documents is discoverable under Rule 16, *Brady*, or on some other basis.
 11 Consistent with that practice—and despite the defense's rejection of the offer—the government
 12 continues its work to obtain and produce the documents Defendants are requesting. Those documents
 13 remain outstanding only because, at this time, the government does not possess the documents in order
 14 to produce them.

15 Defendants lean heavily on the fact that the government previously requested and obtained
 16 documents from FDA and CMS, but this fact cannot be dispositive. It would be problematic if a single,
 17 voluntary production of documents by a third party were sufficient to give the prosecution "access" to
 18 the rest of that party's documents. Under such a system, defendants could obtain unfettered access to
 19 victims' documents through the government, and third parties might hesitate to share any evidence with
 20 criminal investigators.

21 In this case specifically, the facts belie Defendants' claim that FDA and CMS previously gave
 22 the prosecution "carte blanche" access to agency documents. When those agencies shared documents
 23 with the government earlier in the criminal investigation, that access was not unlimited. Indeed, FDA's
 24 letter in response to the prosecution's March 2017 request expressly states that the authorization being
 25 provided by the agency "does not extend to trade secret information, disclosure of which outside the
 26 Department of Health and Human Services is prohibited by law [cite], or to other information disclosure
 27 of which is otherwise prohibited by law or regulation." (Wade Decl. Exh. 7, p.2). That same letter goes
 28 on to remind the prosecution that "FDA's responsive information and records that are exempt from

1 disclosure to the public shall not be further disclosed to other personnel outside of [the prosecution's]
 2 office without FDA's written permission." (*Id.*).

3 The government's supposed access to agency documents is especially tenuous with respect to
 4 CMS. Defendants' motion describes contact between CMS and Theranos, but fails to show meaningful
 5 contact with the prosecution supporting their claim of access. *See United States v. Salyer*, 271 F.R.D.
 6 148, 157 (E.D. Cal. 2010) (denying discovery where "such informal contacts [with the government]
 7 have not risen to the level where the United States Trustee would be considered the 'government' in the
 8 criminal matter"). In sharp contrast to cases where disclosure was ordered, there is no serious argument
 9 here that CMS participated in the criminal investigation of Theranos or Defendants. *Cf. United States v.*
 10 *W.R. Grace*, 401 F. Supp. 2d 1069, 1082 (D. Mont. 2005) (requiring prosecution to produce documents
 11 held by EPA where DOJ and EPA had investigated jointly). Nor is CMS—or FDA, for that matter—as
 12 closely tied to the United States Attorney's Office as are fellow Department of Justice components the
 13 FBI and the Bureau of Prisons. *Cf. United States v. Zuno-Arce*, 44 F.3d 1420, 1427 (9th Cir. 1995)
 14 (prosecution deemed to be in possession of FBI files); *United States v. Santiago*, 46 F.3d 885, 893-94
 15 (9th Cir. 1995) (prosecution had access to BOP files).

16 The primary case Holmes relies on, *United States v. Bryan*, 868 F.2d 1032 (9th Cir. 1989), is
 17 distinguishable. That case involved tax and wire fraud charges arising from a nationwide investigation
 18 of Bryan's activities coordinated by the national office of the IRS. In *Bryan*, The Ninth Circuit rejected
 19 the government's argument that Rule 16 or *Brady* extended only to evidence in the District of Oregon,
 20 where the prosecution was brought. *Id.* at 1036-1037. Here, by contrast, CMS had no involvement in
 21 managing, directing, or executing the criminal investigation, neither the SEC nor the DOJ exercised
 22 such authority over each other, and only the FDA-CI office participated in the criminal investigation.
 23 *See also United States v. Stever*, 603 F.3d 747, 752 (9th Cir. 2010) (government conceded possession of
 24 documents within Rule 16 request).

25 Because Defendants have not shown that the government actually has access to the FDA and
 26 CMS documents described in its motion, the Court should not compel the government to produce these
 27 materials. Instead, the Court should allow the government to continue its efforts to obtain and produce
 28 these documents voluntarily. As described above, FDA and CMS have offered reasonable responses to

1 the requests for additional documents. Should Defendants wish to contest those responses, a Rule 17
 2 subpoena is a more appropriate vehicle than the instant motion.

3 **B. The defense's arguments regarding the content and materiality of the requested
 4 documents are speculative.**

5 Even if Defendants could convince the Court that the government has control over these agency
 6 documents, they still could not meet their burden to establish that the documents are material under the
 7 applicable rules. To obtain discovery under Rule 16, a defendant must make a *prima facie* showing of
 8 materiality. *United States v. Little*, 753 F.2d 1420, 1445 (9th Cir.1984); *see also United States v. Cadet*,
 9 727 F.2d 1453, 1468 (9th Cir.1984) (same). A general description of the information sought will not
 10 suffice, nor will conclusory allegations of materiality. Rather, Defendants must present facts showing
 11 that the government is in possession of information helpful to the defense. *See Little*, 753 F.2d at 1445;
 12 *Cadet*, 727 F.2d at 1466–68; *United States v. Mandel*, 914 F.2d 1215, 1219 (9th Cir.1990); *United States*
 13 *v. Muniz-Jaquez*, 718 F.3d 1180, 1183 (9th Cir.2013); *United States v. Zone*, 403 F.3d 1101, 1107 (9th
 14 Cir.2005).

15 In this case, the defense relies on assumptions to describe the favorable evidence that may be in
 16 the possession of FDA and CMS. For example, Defendants assume that the agencies must possess
 17 additional communications with the journalist whose October 2015 article brought attention to the fraud
 18 at Theranos, and further assume that those communications will show bias on the part of the agencies.
 19 Defendants have failed, however, to present any evidence of actual bias or undue influence in
 20 connection with the agencies' interactions with Carreyrou or any other member of the media. The same
 21 is true with respect to the agencies' contacts with competing laboratories. And even if Defendants could
 22 show that this evidence is likely to exist as they describe, they still could not show materiality under
 23 Rule 16. The Supreme Court has advised that Rule 16 applies primarily to evidence relevant to the
 24 government's case in chief. *United States v. Armstrong*, 517 U.S. 456, 462 (1996). In *Armstrong*, the
 25 Supreme Court held that the defense was not entitled to discovery to prove a selective-prosecution claim
 26 because it "is not a defense on the merits of the criminal charge" and "asks a court to exercise judicial
 27 power over a 'special province of the Executive.'" *Id.* at 464. Similarly, here, Defendants' speculative
 28 bias theory regarding FDA and CMS is too far afield from the subject matter of the government's case in

1 chief. Insofar as the case in chief involves FDA, it relates to *what Defendants' knew and what FDA told*
 2 *them* with respect to approval requirements. The agency's underlying motives are beside the point—and
 3 Defendants have provided no real reason to question them. As the court in *Armstrong* reasoned, “the
 4 showing necessary to obtain discovery should itself be a significant barrier to the litigation of
 5 insubstantial claims.” *Id.*

6 Moreover, as set forth in FDA's and CMS's response letters, Defendants' document requests are
 7 broad and burdensome. The agencies will be required to expend substantial resources in order to locate,
 8 review, and produce responsive materials. Under these circumstances, courts apply extra scrutiny to the
 9 question of materiality, and deny motions to compel where the documents in question would be unduly
 10 burdensome to produce. *See Mandel*, 914 F.2d at 1219; *Cadet*, 727 F.2d at 1468 (discovery request was
 11 so far ranging and potentially burdensome that it was an abuse of discretion to grant). Defendants'
 12 overbroad and speculative requests cannot survive scrutiny under this standard. Accordingly, the Court
 13 should deny Defendants' motion and permit FDA and CMS to make a reasonable document production
 14 in response to the pending requests made voluntarily by the government.

15 **C. The government has no obligation to obtain and produce documents held by state
 16 agencies not involved in the criminal investigation.**

17 Even if Defendants could make the showing necessary to compel the prosecution to obtain
 18 discovery from the federal agencies named in their motion, the law is clear that this same reasoning
 19 would not apply to documents held in the possession of state agencies.

20 In *United States v. Fort*, 478 F.3d 1099 (9th Cir.2007), the Ninth Circuit held that the
 21 government is not deemed “to have knowledge or access to anything generated by a state or local actor
 22 that is not actually known by and in the possession of the prosecutor.” *Id.* at 1100. Citing an earlier
 23 decision, the Ninth Circuit in that case confirmed that the opinion “establishes no principle of
 24 constructive possession” in this context. *Id.*; *see also United States v. Chavez-Vernaza*, 844 F.2d 1368,
 25 1375 (9th Cir.1988) (“[T]he federal government had no duty to obtain from state officials documents of
 26 which it was aware but over which it had no actual control.”); *United States v. Gatto*, 763 F.2d 1040 (9th
 27 Cir. 1985) (evidence found and held by state authorities became discoverable only when federal
 28 authorities gained physical possession; “the triggering requirement under Rule 16(a)(1)(E) is that the...

1 tangible objects be in the actual possession... of the government"). Simply put, the government "is not
 2 obligated to review state law enforcement files not within its possession or control." *United States v.*
 3 *Dominguez-Villa*, 954 F.2d 562, 566 (9th Cir.1992). These principles defeat Defendants' claim as to all
 4 documents in the custody of the California Department of Public Health. That CMS has nonetheless
 5 agreed to produce responsive documents from CDPH merely underscores the fact that a court order
 6 compelling this production is unnecessary.

7 **D. The government has already produced discoverable materials received from SEC.**

8 While the prosecution and its case agents have conducted an investigation of the criminal fraud
 9 that occurred at Theranos, SEC has conducted its own, parallel investigation into attendant violations of
 10 securities laws by these same Defendants. Although the investigations were independent, driven by
 11 different aims and governed by different standards, the prosecution and SEC coordinated aspects of their
 12 investigations for the sake of efficiency. The primary benefit of this coordination was to reduce the
 13 burden on third-party witnesses and document custodians common to the two investigations. Witnesses
 14 who would otherwise sit for separate interviews with the prosecution and SEC experienced less
 15 inconvenience through that coordination. Similarly, document custodians who might otherwise be
 16 required to produce Theranos-related documents to the prosecution and SEC independently saved time
 17 and expense to the extent documents were shared between the criminal and civil investigations. The
 18 government has produced to the defense all of the discovery documents shared by the SEC, along with
 19 reports in the government's possession memorializing witness interviews conducted by the prosecution
 20 and SEC. Defendants claim to be dissatisfied with this disclosure, and now seek to compel the
 21 prosecution to produce notes and other documents held by the SEC. This request from the defense is
 22 unreasonable in light of the fact that the government does not have possession, custody, or control over
 23 the SEC's notes and other internal documents. Moreover, those documents clearly represent the
 24 attorney work product of counsel for an entity currently in active litigation against one of the
 25 Defendants. Defendants' argument also ignores that such documents are not discoverable under the
 26 Federal Rules of Criminal Procedure, which state that the Rule 16:

27 ... does not authorize the discovery or inspection of reports, memoranda, or other
 28 internal government documents made by an attorney for the government or other

1 government agent in connection with investigating or prosecuting the case. Nor
 2 does this rule authorize the discovery or inspection of statements made by
 3 prospective government witnesses except as provided in 18 U.S.C. § 3500.
 4 Fed. R. Crim. P. 16(a)(2).

5 In addition to Rule 16's limits, the Dodd-Frank Act makes it clear that the SEC does not waive
 6 its work product and other privileges by sharing information with DOJ. *See* 15 U.S.C. § 78x(f)(1)(A)
 7 ("The [SEC] shall not be deemed to have waived any privilege applicable to any information by
 8 transferring that information to or permitting that information to be used by any agency . . .") & 18
 9 U.S.C. § 6 (defining agency to include any department of the United States).

10 Despite the principles above, the government will seek to review SEC's witness interview notes
 11 for *Brady* material. This measure exceeds the government's obligations and should be more than
 12 sufficient to protect Defendants' interests. Accordingly, the Court should deny Defendants' motion, and
 13 Defendants must settle for what the law entitles them to—namely, the discoverable evidence in this
 14 case. *See SEC v. Reyes*, No. C 06-04435 CRB, 2007 WL 528718, at *4 (N.D. Cal. Feb. 13, 2007)
 15 ("Defendant Reyes may be entitled to all exculpatory evidence, but he cites no authority for the
 16 proposition that he is entitled to have any document revealing what attorneys at the SEC or DOJ *think*
 17 about such evidence"); *see also United States v. Tealer*, 2015 U.S. Dist. LEXIS 157954, at *2 (D. Neb.
 18 Nov. 23, 2015) (denying *Brady* request for internal documents, as "Defendant has pointed to no
 19 authority supporting the proposition that *Brady* requires the production of internal government
 20 documents which simply discuss evidence").

21 **E. An order requiring the government to comply with its discovery obligations is
 22 unnecessary and impracticable.**

23 Several of Defendants' arguments ask the Court to compel the government to abide by discovery
 24 obligations that the government already intends to fulfill. As to those arguments, the Court should
 25 decline to issue such a superfluous order, consistent with the case law discussing these discovery
 26 obligations. At the same time, however, several of Defendants' demands go well beyond what the law
 27 requires of the government, and the Court should decline to issue Defendants' proposed order on that
 28 basis as well. Both of these problems infect Defendants' request for reports, notes, correspondence, and

1 other materials regarding communications with witnesses.

2 The government's *Brady* obligation is a "self-executing responsibility on the part of the
3 prosecutor.... [T]here is no need for a court order to require compliance with *Brady*." *United States v.*
4 *Flores*, No. 08-0730-WHA, 2011 WL 1100137, at *1 (N.D.Cal. Mar. 24, 2011); *see also United States*
5 *v. Lucas*, 841 F.3d 796, 807 (9th Cir. 2016) ("it is the government, not the defendant or the trial court,
6 that decides *prospectively* what information, if any, is material and must be disclosed under *Brady*";
7 "Brady does not permit a defendant to sift through information held by the government to determine
8 materiality."); *see also United States v. Jennings*, 960 F.2d 1488, 1491-92 (9th Cir. 1992) (admonishing
9 courts to avoid interfering with executive branch's *Brady* obligations unless there is "a clear basis in law
10 or fact to believe that [interference is] necessary....").

11 In this case, the government has consistently produced to the defense FBI 302s and other similar
12 investigatory reports memorializing relevant information provided to the government during witness
13 interviews. The government will continue to abide by this practice, and there is no need for the Court to
14 mandate it. To address Defendants' stated concerns regarding *Brady* material in this context, the
15 government has agreed to make available to the defense agent notes of witness interviews, so that the
16 defense can conduct its own review and confirm the absence of any material inconsistencies. This step
17 exceeds the government's discovery obligations under the standards discussed above, especially in light
18 of the fact that such notes are expressly not discoverable under Federal Rule of Criminal Procedure
19 16(a)(2), quoted above.

20 //

21

22

23

24

25

26

27

28

1 **IV. CONCLUSION**

2 The relief sought by Defendants in the instant motion is unnecessary and improper. For the
3 foregoing reasons, the Court should deny Defendants' motion to compel in its entirety.

4

5

6 DATED: June 12, 2019

Respectfully submitted,

7 ADAM A. REEVES
8 Attorney for the United States
9 Acting Under Authority Conferred
by 28 U.S.C. § 515

10 /S/
11 JEFF SCHENK
12 JOHN C. BOSTIC
13 ROBERT S. LEACH
14 Assistant United States Attorneys